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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,722	01/11/2002	Emanuel DiCicco-Bloom	270/175US	1548

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EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,722	DICICCO-BLOOM ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) 16-21 is/are objected to.

8)☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 16 – 21 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The above-listed claims depend from claim 10, which is drawn to the use of PACAP. However, the dependent claims are written as if claim 10 is drawn to the use of PACAP and a PACAP agonist, whereas no mention of an agonist is made in claim 10. Claim 14 recites the use of PACAP and an agonist. For the purposes of this Office action, the examiner has assumed that claims 16 – 21 depend from claim 14.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 – 6 and 39 – 45, drawn to methods of proliferating neuronal precursor cells by administering $PACAP_{6-38}$, classified in class 514, subclass 12.

II. Claims 1 – 4, 7, 8, and 39 – 45, drawn to methods of proliferating neuronal precursor cells by administering max d 4, classified in class 514, subclass 12.

III. Claims 1 – 4, 9, and 39 – 45, drawn to methods of proliferating neuronal precursor cells by administering a non-metabolizable antagonist, classification dependent upon structure.

IV. Claims 10 – 13, 15, 22 - 25, and 33 – 38, drawn to methods of inhibiting proliferation of neuronal precursor cells by administering PACAP, classified in class 514, subclass 12.

V. Claims 14, 16, and 17, drawn to methods of inhibiting proliferation of neuronal precursor cells by administering PACAP and maxadilan, classified in class 514, subclass 12.

VI. Claims 14, 18, and 19, drawn to methods of inhibiting proliferation of neuronal precursor cells by administering PACAP and $PACAP_{27}$, classified in class 514, subclass 12.

VII. Claims 14, 20, and 21, drawn to methods of inhibiting proliferation of neuronal precursor cells by administering PACAP and VIP, classified in class 514, subclass 12.

VIII. Claims 26 – 29 and 39 – 45, drawn to methods of promoting proliferation of neuronal precursor cells by administering oligonucleotides, classified in class 514, subclass 44.

IX. Claims 30 – 32 and 39 – 45, drawn to methods of promoting proliferation of neuronal precursor cells by administering antibodies, classified in class 424, subclass 139.1.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:

Inventions I, II, and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Invention I require different starting materials from the methods of Inventions II and III, even thought they have similar steps and goals. Because the Inventions require patentably distinct starting materials, they are independent and distinct inventions.

Inventions I – III are not related to Inventions IV – VII because the methods have different starting materials, steps and goals. Inventions I – III are drawn to methods of proliferating neuronal precursor cells, whereas Inventions IV – VII are drawn to methods of inhibiting proliferation. Furthermore, the methods use different chemical compounds, which would necessitate separate searches, constituting a burden upon the Office.

Inventions I – VII and IX are distinct and independent from Invention VIII. Invention VIII is drawn to methods of genetic therapy, which are unrelated to any other Invention. Oligonucleotides are not required for any of the other methods of proliferating or inhibiting the proliferation of neuronal precursor cells, or for treating medical conditions. Furthermore, methods of gene therapy are classified separately, reflecting their unique status in the art.

Inventions I – VII are distinct and independent from Invention IX. The method of Invention IX requires the use of antibodies to PACAP, which is not required for any of the other inventions. The use of antibodies has a different status in the art, as reflected by its independent classification.

Inventions IV, V, VI, and VII are distinct and independent from each other because they require different patentably distinct starting materials. Inventions V, VI and VII require the administration of distinct agonists in addition to PACAP. Consideration of these Inventions would require additional searches, thereby placing a burden on the Office.

Requirement for Further Restriction Within Inventions I - III, VIII, and IX

Claim 44 recites numerous diseases. Should Applicant elect Invention I – III, VIII, or IX, further restriction is required. Applicant must elect one of the following diseases:

a) either hemorrhagic or ischemic stroke

b) a specific dementia

c) a specific primary cortical degenerative disorder

d) a specific sub-cortical degenerative disorder

e) a specific infection

f) a specific prion disorder

g) a specific toxic disorder

h) a specific metabolic disorder

i) a specific brain injury

Applicant is advised that this is not a species election. Consideration of all diseases simultaneously would require multiple searches, as the literature describing the etiology and treatment of these diseases is vast and diverse.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call was made to Jane Licata on October 26, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eileen B. O'Hara

Daniel E. Kolker, Ph.D.

EILEEN B. O'HARA
PATENT EXAMINER